

REMARKS/ARGUMENTS

Claims 1-20 remain in this application. As suggested in the Office Action, claims 1, 2, and 14 have been amended, without prejudice, to recite the units of “Daltons” for the molecular weight. New claims 18-20 have been added. Support for these new claims can be found in original claim 4 and page 9, line 35 to page 10, line 2. Accordingly, no issues of new matter are believed to be raised by the above amendments to the claims.

Rejection Under 35 USC 112

Claims 1-5 and 7-17 were rejected under 35 USC 112, second paragraph, as being indefinite. See Page 3 of the Office Action. According to the Office Action, “Claims 1, 2, and 14 recite a weight average molecular weight without providing units for the molecular weight.” See Page 3 of the Office Action. Applicants respectfully disagree, but in the interests of furthering this application to allowance, as discussed above, Applicants have amended, without prejudice, claims 1, 2, and 14 to recite the units of “Daltons” for the molecular weight. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Rejections Under 35 USC 103

Claims 1-5 and 7-17 were rejected under 35 USC 103(a) as being unpatentable over Reuter et al (US Patent No. 4,835,187) in view of Lachman et al. and Chau et al. (US5637313). See Pages 4-7 of the Office Action. According to the Office Action,

“Reuter et al. teach an immediate release composition in chewable solid dosage form. . . . Reuter et al do not teach the composition comprising the matrix comprising the hydroxypropylmethylcellulose. However, Chau et al teach the formation of a soft, chewable, tablet dosage form wherein the components. . . may be incorporated in the matrix during mixing or thereafter. . . . Also, Reuter et al do not explicitly teach the instantly claimed particle diameters ranging from about 150 μm to about 400 μm . However, Lachman et al. teach to systematically adjust the diameters of said particles during the course of routine experimentation so as to obtain a free-flowing composition exhibiting desired flow properties that are suitable for manufacturing processing. . . . Therefore, it would have been prima facie obvious for one skilled in the art at the time of

the invention to make a soft, chewable tablet with a plurality of particles containing ibuprofen and hydroxypropylmethylcellulose. . . .”

See Pages 4-5 of the Office Action. Applicants respectfully disagree.

As noted above in the Office Action, “Reuter et al do not teach the composition comprising the matrix comprising the hydroxypropylmethylcellulose.” Chau et al. merely discloses the broad class of “hydroxymethylcellulose” in a broad class of water-soluble bulking agents. See col. 3, line 65 through col. 4., line 11 of Chau et al. Chau et al., thus, does not disclose, or even suggest, the use of 0.1 percent to about 25 percent of hydroxyalkylcellulose having a weight average molecular weight of from about 60,000 to about 5,000,000 and/ or a viscosity of from about 3,000 mPa.S to about 150,000 mPa.s in a 2% aqueous solution as recited in the pending claims. In fact, alkylcelluloses are not listed as preferred water-soluble bulking agents by Chau et al. See col. 4., lines 7-11 of Chau et al. Therefore, one skilled in the art at the time of the invention would not look to Chau et al. to use the recited amount of the specifically recited hydroxyalkyl cellulose in the matrix of the immediate release dosage form of the pending claims. Similarly, Lachman et al. also fails to teach, or suggest, the use of such hydroxyalkylcellulose in the matrix of the immediate release dosage form of the pending claims.

Further, as noted on page 11, lines 3-6 of the application, Applicants “unexpectedly found that the addition of high weight average molecular weight hydroxyalkylcellulose to the matrix results in a dosage form that delivers a good mouthfeel through a rapid viscosity build without an initial intense drying sensation of the mouth and without a subsequent excessive slimy or gummy feel during mastication.”

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time of the claims invention was made in light of these references. Thus, Applicants respectfully request that this rejection under 35 USC 103(a) be withdrawn.

Conclusion

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the amended claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/MCP-5016/WEM.

Respectfully submitted,

By: _____/William E. McGowan/_____
William E. McGowan
Reg. No. 39,301

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2197